

CLAIMS

1. A controller for a blood treatment equipment, said equipment comprising at least a treatment unit including a semipermeable membrane separating the treatment unit in a first compartment for the circulation of blood and in a second compartment for the circulation a of a treatment liquid,

the controller being adapted to:

receive one or more entries of measured information measured during the course of a treatment procedure,

calculate from said measured information a value of at least a significant parameter indicative of the progress of an extracorporeal blood treatment carried out by the equipment,

wherein the controller is also adapted to compare said calculated significant parameter to at least a prescribed reference value for the same parameter, and to generate at least one output control signal responsive to said comparison for automatically controlling one or more operations performed by the equipment.

2. Controller according to claim 1, wherein the significant parameter is one chosen in the group comprising:

- the actual dialysance D_{Ti} or clearance K_{Ti} of a blood treatment unit associated with the equipment for a specific solute after a time T_i elapsed from the beginning of the treatment;

- the concentration of a substance in the blood of a patient undergoing a treatment or the patient's plasmatic conductivity C_{pT_i} achieved at the elapsed time T_i ;
 - the dialysis dose $K^*T_{T_i}$ achieved at the elapsed time T_i ;
 - 5 - the weight loss WL_{T_i} achieved at the elapsed time T_i ;
 - a parameter proportional or known function of one or more of the above parameters.
3. Controller according to claims 1 or 2, wherein said measured information is one
- 10 chosen in the group comprising:
- conductivity of the of the treatment liquid downstream the treatment unit;
 - concentration of a substance in the treatment liquid downstream the treatment unit.
- 15 4. Controller according to claim 1, wherein the controller generates the output control signal responsive to said comparison for automatically controlling a fluid removal rate from said second compartment.
5. Controller according to anyone of claims from 1 to 4, wherein the prescribed
- 20 reference value comprises the total dialysis dosage value KT_p to be achieved at the end of the treatment, said controller determining, at time intervals during treatment:
- o an instantaneous clearance K_{T_i} or dialysance value D_{T_i} measured at treatment time T_i ,

- an effective total dialysis dosage KT_{Ti} value which has been delivered at the elapsed treatment time T_i ,
 - at least one among an estimated remaining treatment procedure time T_{tr} and an estimated total treatment time T_{tot} required for achieving said prescribed total dialysis dosage value KT_p .
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6. Controller according to claim 5, wherein said controller is programmed for determining the estimated remaining treatment procedure time T_{tr} as a function of said total dialysis dosage value KT_p , the effective total dialysis dosage KT_{Ti} achieved by time T_i , and of the instantaneous clearance K_{Ti} or dialysance value D_{Ti} measured at treatment time T_i .

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7. Controller according to claim 5, wherein said controller is programmed for determining the estimated total treatment time T_{tot} as a function of said total dialysis dosage value KT_p , of the effective total dialysis dosage KT_i achieved by time T_i , and of the elapsed treatment time T_i .

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8. Controller according to claim 6, wherein said controller, at each time interval, is programmed for updating the estimated total treatment time T_{tot} as sum of the elapsed treatment time T_i and of the estimated value of the remaining treatment procedure time T_{tr} .

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9. Controller according to claim 6 or 7, wherein said prescribed parameter also comprises a prescribed total weight loss WL_p to be achieved at the end of the

treatment, said controller being programmed for performing the following further steps at time intervals during treatment:

- determining of an actual measured total weight loss WL_{Ti} achieved by time T_i ,
- 5 ○ setting of fluid removal rate UF from said second compartment for achieving a prescribed total weight loss WL_p substantially at the same time as the prescribed total dialysis dosage value KT_p is achieved.

10. Controller according to claim 9, wherein it is programmed for controlling, on an ongoing basis, the fluid removal rate as a function of the estimated remaining treatment procedure time T_{tr} or of estimated total treatment time T_{tot} .

11. Controller according to claim 10, wherein said controlling comprises setting of the fluid removal rate UF_{Ti} at time T_i equal to the prescribed total weight loss WL_p less the measured weight loss WL_{Ti} at time T_i , divided by the estimated remaining treatment time T_{tr} , according to the formula:

$$UF_{Ti} = \frac{WL_p - WL_{Ti}}{T_{tr}}$$

12. Controller according to claim 10, wherein said controlling step comprises setting of the fluid removal rate UF_{Ti} at time T_i equal to the prescribed total weight loss WL_p less the measured weight loss WL_{Ti} at time T_i , divided by a difference between the estimated total treatment time T_{tot} and the elapsed treatment time T_i according to the formula: $UF_{Ti} = \frac{WL_p - WL_{Ti}}{T_{tot} - T_i}$

$$T_{tot} - T_i$$

13. Controller according to anyone of claims from 5 to 13, wherein it is programmed for recalculating and updating at regular time intervals during treatment the estimated total treatment time T_{tot} and/or the estimated remaining treatment time T_{tr} , on the basis of the most recent value or values of instantaneous clearance K_{Ti} or dialysance D_{Ti} .

14. Controller according to anyone of claims from 5 to 13, wherein it is programmed for recalculating and updating at regular time intervals during treatment the effective total dialysis dosage KT_{Ti} value, which has been delivered at the elapsed effective treatment time T_i .

15. Controller according to claim 5, wherein the instantaneous clearance value K_{Ti} or instantaneous dialysance value D_{Ti} is determined at treatment time T_i , by means of the following sub-steps:

- sending at least a first liquid through the second compartment of the treatment unit,
- sending at least a second liquid through the second compartment of the treatment unit, the second liquid having conductivity or concentration for at least a solute different from that of the first liquid
- measuring the conductivity or concentration values of said substance in the treatment liquid downstream the treatment unit at least for both said first and for said second liquid,

- calculating the instantaneous clearance K_{Ti} or instantaneous dialysance value D_{Ti} at least as a function of said measured conductivity or concentration values.

5 16. Controller according to claim 5, wherein the effective total dialysis dosage KT_{Ti} value, which has been delivered at the determined effective treatment time T_i , is calculated as an integration over time of effective instantaneous clearance K_{Ti} or instantaneous dialysance D_{Ti} values determined at the various regular time intervals T_i .

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17. Controller according to claim 5, wherein the effective total dialysis dosage KT_i value, which has been delivered at the effective treatment time T_i , is calculated as the product of the treatment time T_i by a mean value of effective instantaneous clearance K_{Ti} or of instantaneous dialysance D_{Ti} values determined at the various
15 regular time intervals T_i .

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18. Controller according to anyone of claims from 1 to 4, wherein the prescribed parameter comprises the total clearance value KT_p to be achieved at the end of the treatment, and a prescribed total weight loss WL_p to be achieved at the end of the treatment, said controller being programmed for determining a prescribed rate R by dividing said total weight loss WL_p to be achieved at the end of the treatment by said total dialysis dose value KT_p to be achieved at the end of the treatment.

19. Controller according to claim 14, wherein it is programmed for controlling the rate of fluid removal from the second compartment of the blood treatment, said controlling comprising keeping said rate of fluid removal UF_{Ti} at time T_i substantially equal to the product of said prescribed rate R by the instantaneous clearance K_{Ti} or instantaneous dialysance value D_{Ti} measured at treatment time T_i .

20. Controller according to claim 5, wherein said controller, at each time interval, is programmed for:

- calculating a sum of the elapsed treatment time T_i with the calculated value of the remaining treatment procedure time T_r .
- comparing said sum with a minimum treatment time T_{min} and with a maximum treatment time T_{max}
- setting a total treatment time T_{tot} equal to the minimum treatment time T_{min} , if said sum is less than the minimum treatment time T_{min} ,
- setting a total treatment time T_{tot} equal to the maximum treatment time T_{max} , if said sum is more than the minimum treatment time T_{min} ,
- setting a total treatment time T_{tot} equal to said sum if the sum is neither less than the minimum treatment time T_{min} nor more than the minimum treatment time T_{max} .

21. Controller according to claim 20, wherein said prescribed parameter also comprises a prescribed total weight loss WL_p to be achieved at the end of the treatment, said controller being programmed for performing the following further steps at time intervals during treatment:

- determining of an actual measured total weight loss WL_{Ti} achieved by time T_t ,
- setting of fluid removal rate from said second compartment for achieving a prescribed total weight loss WL_p at said total treatment time T_{tot} .

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22. Controller according to claim 21, wherein it is programmed for controlling, on an ongoing basis, the fluid removal rate UF_{Ti} at time T_i as a function of the total treatment time T_{tot} by setting the UF_{Ti} fluid removal rate at time T_i equal to the prescribed total weight loss WL_p less the measured weight loss WL_{Ti} at time T_i , divided by the difference between the calculated total treatment time T_{tot} and the elapsed treatment time T_i , according to the formula:

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$$UF_{Ti} = \frac{WL_p - WL_{Ti}}{T_{tot} - T_i}$$

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23. Controller according to claim 21, wherein it is programmed for recalculating and updating the total treatment time T_{tot} and/or the remaining treatment time T_r at regular time intervals during treatment, on the basis of the last or most recent instantaneous measured value or values of clearance K_{Ti} or dialysance D_{Ti} .

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24. Controller according to claim 21, wherein it is programmed for recalculating and updating at regular time intervals during treatment the effective total dialysis dosage KT_{Ti} value which has been delivered at the elapsed effective treatment time T_i .

25. Controller according to claim 21, wherein the effective total dialysis dosage KT_t value, which has been delivered at the determined effective treatment time T_i , is calculated as an integration over time of effective instantaneous dialysis dosage values D_{Ti} determined at the various regular time intervals T_i .

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26. Controller according to claim 1 or 5 or 18 or 20, wherein the prescribed reference value comprises a patient blood conductivity or concentration target $C_{p_{end}}$, said controller being programmed for controlling the conductivity or concentration of the treatment liquid entering the second compartment as a function
10 of said blood conductivity or concentration target $C_{p_{end}}$.

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27. Controller according to claim 5, wherein the prescribed reference value comprises a patient blood conductivity or concentration target $C_{p_{end}}$ to be achieved, said controller being programmed for changing, if necessary, at each time interval,
the conductivity or concentration of the treatment liquid entering the second
compartment in order to have blood conductivity or concentration for a substance
reaching said conductivity or concentration target $C_{p_{end}}$ on or before said estimated
total treatment time T_{tot} .

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28. Controller according to claim 9, wherein the prescribed reference value comprises a patient blood conductivity or concentration target $C_{p_{end}}$ to be achieved, said controller being programmed for changing, if necessary, at each time interval,
the conductivity or concentration of the treatment liquid entering the second
compartment in order to have blood conductivity or concentration for a substance

reaching said conductivity or concentration target $C_{p_{end}}$ on or before said estimated total treatment time T_{tot}

29. Controller according to anyone of claims from 5 to 25, wherein the prescribed
5 reference value comprises a patient blood conductivity or concentration target $C_{p_{end}}$ to be achieved, said controller being programmed for performing the following steps at each time interval t_i during at least a part of said treatment:

- determining an interval target blood conductivity or concentration C_{p_i} for the patient's blood, relating to a elapsed time T_i
- 10 ○ modifying, if necessary, the conductivity or concentration for a substance C_d of treatment liquid entering the second compartment to have the patient plasmatic conductivity reaching the interval target C_{p_i} .

15 30. Controller according to claim 29, wherein the said modifying of treatment liquid conductivity or concentration C_d comprises the following sub-steps:

- iii. Determining a calculated value C_{di} of the conductivity or concentration for a substance C_d as a function of the interval target C_{p_i} and of the measured instantaneous dialysance or clearance D_i or K_i for time T_i ,
- 20 iv. Bringing the conductivity or concentration for a substance C_d of treatment liquid entering the second compartment to said calculated value C_{di}

31. Controller according to claim 30, wherein the said determining step uses the following formula:

$$C_d = C_{di} = \frac{C_{Pi} - C_{Pi-1} e^{-\frac{D_i}{V_0}(T_i - T_{i-1})}}{1 - e^{-\frac{D_i}{V_0}(T_i - T_{i-1})}}$$

wherein V_0 represents the urea distribution volume for the patient.

5 32. Controller according to claim 30, wherein the said determining step uses the following formula:

$$C_d = C_{di} = \frac{C_{Pi} - C_{Pi-1} e^{-\frac{K_i}{V_0}(T_i - T_{i-1})}}{1 - e^{-\frac{K_i}{V_0}(T_i - T_{i-1})}}$$

wherein V_0 represents the urea distribution volume for the patient.

33. Controller according to claim 29, wherein it is programmed for calculating said
10 interval target blood conductivity or concentration C_{Pi} for the patient's blood relating to a time interval t_i , according to the following steps:

- evaluating if the elapsed treatment time T_i is more or less of a prescribed value T_p ,
- assigning as interval target blood $C_{Pi} = C_{p_{end}} + A$, wherein A is a positive
15 value, if T_i less than T_p
- assigning as interval target blood $C_{Pi} = C_{p_{end}}$, if T_i more than or equal to T_p .

34. Controller according to claim 33, wherein the prescribed value T_p is less than T_{tot} .

35. Controller according to claim 34, wherein the prescribed value T_p is equal to T_{tot} reduced by one hour.

5 36. Blood treatment equipment comprising at least a treatment unit including a semipermeable membrane separating the treatment unit in a first compartment for the circulation of blood and in a second compartment for the circulation a of a treatment liquid, and a controller according to anyone of the preceding claims.

10 37. Equipment according to claim 36, comprising measuring means connected to the controller for measuring at least one of:
conductivity of the of the treatment liquid downstream the treatment unit; or
concentration of a substance in the treatment liquid downstream the treatment unit.

15 38. Equipment according to claim 36, comprising measuring means for measuring at least one of:
conductivity of the of the treatment liquid upstream the treatment unit; or
concentration of a substance in the treatment liquid upstream the treatment unit.

20 39. Equipment according to claim 37, comprising measuring means for measuring comprises a conductivity cell or an ion selective sensor or a urea sensor, operating on a conduit downstream the treatment unit.

40. Equipment according to claim 38, comprising measuring means for measuring comprises a conductivity cell or an ion selective sensor, operating on a conduit upstream the treatment unit.

5 41. Equipment according to claim also including entry means for entering prescribed reference value or values for the significant parameter or parameters.

42. Equipment according to claim 36, comprising a variable speed ultrafiltration pump, in which the controller is programmed to generate a control signal to
10 automatically control the fluid removal rate from said second compartment, by controlling the variable speed ultrafiltration pump.

43. Equipment according to claim 36, wherein the controller is associated with an alert device, and the controller is programmed to activate said alert device if the
15 expected treatment procedure time or remaining hemodialysis treatment time are not within a prefixed range.

44. Equipment according to claim 18, in which the controller is associated with a display screen adapted to display at the time intervals T_i one or more of the values
20 of the group comprising:

- remaining time T_{tr} ,
- total treatment time T_{tot} ,
- clearance of dialysance measurements at the elapsed time T_i ,
- achieved dialysis dosage KT_{Ti} after T_i time,

- achieved weight loss WL_{Ti} after T_i time,
- achieved patient's conductivity after T_i time,
- prescribed value for more of the significant parameters,
- a value proportional to one or more of the above values.

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45. A control method for a blood treatment equipment, said equipment comprising at least a treatment unit including a semipermeable membrane separating the treatment unit in a first compartment for the circulation of blood and in a second compartment for the circulation a of a treatment liquid,

10 the method comprising the steps:

receiving one or more entries of measured information measured during the course of a treatment procedure,

calculating from said measured information a value of at least a significant parameter indicative of the progress of an extracorporeal blood treatment carried out by the equipment,

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comparing said calculated significant parameter to at least a prescribed reference value for the same parameter, and generating at least one output control signal responsive to said comparison for automatically controlling one or more operations performed by the equipment.

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46. Method according to claim 45, wherein the significant parameter is one chosen in the group comprising:

- the actual dialysance D_{Ti} or clearance K_{Ti} of a blood treatment unit associated with the equipment for a specific solute after a time T_i elapsed from the beginning of the treatment;
- the concentration of a substance in the blood of a patient undergoing a treatment or the patient's plasmatic conductivity Cp_{Ti} achieved at the elapsed time T_i ;
- the dialysis dose $K \cdot T_{Ti}$ achieved at the elapsed time T_i ;
- the weight loss WL_{Ti} achieved at the elapsed time T_i ;
- a parameter proportional or known function of one or more of the above parameters.

47. Method according to claims 45 or 46, wherein said measured information is one chosen in the group comprising:

- conductivity of the of the treatment liquid downstream the treatment unit;
- concentration of a substance in the treatment liquid downstream the treatment unit.

48. Method according to claim 1, wherein the controller generates the output control signal responsive to said comparison for automatically controlling a fluid removal rate from said second compartment.

49. Method according to anyone of claims from 45 to 48, wherein the prescribed reference value comprises the total dialysis dosage value KT_p to be achieved at the

end of the treatment, said method comprising the step of determining, at time intervals during treatment:

- an instantaneous clearance K_{Ti} or dialysance value D_{Ti} measured at treatment time T_i ,
- an effective total dialysis dosage KT_{Ti} value which has been delivered at the elapsed treatment time T_i ,
- at least one among an estimated remaining treatment procedure time T_{tr} and an estimated total treatment time T_{tot} required for achieving said prescribed total dialysis dosage value KT_p .

50. Method according to claim 49, wherein it comprises recalculating and updating at regular time intervals during treatment the estimated total treatment time T_{tot} and/or the estimated remaining treatment time T_{tr} , on the basis of the most recent value or values of instantaneous clearance K_{Ti} or dialysance D_{Ti} .

51. Method according to anyone of claims from 49, wherein it comprises recalculating and updating at regular time intervals during treatment the effective total dialysis dosage KT_{Ti} value, which has been delivered at the elapsed effective treatment time T_i .

52. Method according to claim 49, wherein the effective total dialysis dosage KT_{Ti} value, which has been delivered at the determined effective treatment time T_i , is calculated as an integration over time of effective instantaneous clearance K_{Ti} or

instantaneous dialysance D_{Ti} values determined at the various regular time intervals T_i .

53. Method according to claim 49, wherein the effective total dialysis dosage KT_i value, which has been delivered at the effective treatment time T_i , is calculated as the product of the treatment time T_i by a mean value of effective instantaneous clearance K_{Ti} or of instantaneous dialysance D_{Ti} values determined at the various regular time intervals T_i .

54. Method according to claim 45, wherein the prescribed parameter comprises the total clearance value KT_p to be achieved at the end of the treatment, and a prescribed total weight loss WL_p to be achieved at the end of the treatment, said method including the steps of determining a prescribed rate R by dividing said total weight loss WL_p to be achieved at the end of the treatment by said total dialysis dose value KT_p to be achieved at the end of the treatment.

55. Method according to claim 45 or 54, wherein the prescribed reference value comprises a patient blood conductivity or concentration target $C_{p_{end}}$, said method including the steps of controlling the conductivity or concentration of the treatment liquid entering the second compartment as a function of said blood conductivity or concentration target $C_{p_{end}}$.

56. Method according to claim 45, wherein the prescribed reference value comprises a patient blood conductivity or concentration target $C_{p_{end}}$ to be achieved,

said method including the steps of changing, if necessary, at each time interval, the conductivity or concentration of the treatment liquid entering the second compartment in order to have blood conductivity or concentration for a substance reaching said conductivity or concentration target $C_{p_{end}}$ on or before said estimated
5 total treatment time T_{tot} .

57. Method according to claim 54, wherein the prescribed reference value comprises a patient blood conductivity or concentration target $C_{p_{end}}$ to be achieved, said controller being programmed for changing, if necessary, at each time interval,
10 the conductivity or concentration of the treatment liquid entering the second compartment in order to have blood conductivity or concentration for a substance reaching said conductivity or concentration target $C_{p_{end}}$ on or before said estimated total treatment time T_{tot}

15 58. Program storage means including a program for a programmable controller, the program when run by the controller programming the controller to carry out the steps according to the preceding method claims.

59. Program storage means according to claim 58 comprising an optical data
20 carrier and/or a magnetic data carrier and or a volatile memory support.